GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1146
ANSWERED ON:29.04.2016
Ban of Drugs
Mahadik Shri Dhananjay Bhimrao;Sule Smt. Supriya Sadanand

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has banned Liposomal Amphotericin B, an injection based drug used to treat potentially life threatening fungal infection including meningitis;

(b) if so, the details thereof and the reasons therefor;

(c) whether the Government has consulted the drug companies before imposing the ban on the drug;

(d) if so, the details thereof; and

(e) the corrective steps taken by the Government in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)
(a) & (b): The Central Drugs Standard Control Organisation had, on 11.03.2016, requested the State Licensing Authorities concerned to suspend the licenses of 10 manufacturers of Liposomal Amphotericin B in public interest with immediate effect. This was done after examination by an expert Committee of the data regarding the quality, safety and efficacy of Liposomal Amphotericin B where submitted by these manufacturers. The expert Committee had observed that the safety and efficacy of the products had not been established.
(c) to (e): All the manufacturers of Lipid/Liposomal Amphotericin B Injection were asked to prove quality, safety and efficacy of their products on the basis of criteria determined by the Committee. Show cause notices were issued to these manufacturers asking them as to why the manufacturing licenses issued to them for Liposomal Amphotericin B Injection should not be suspended. Out of 10 manufacturers, only 07 responded and, after due consideration of their replies, it was found that their responses were not sufficient to conclude that the products are safe and efficacious. The suspension of the licence will ensure that drugs of unproven safety and efficacy are not marketed.